K053511

MAR 10 2006

510(k) Summary for the Femtosecond Laser Microkeratome

Device trade name: Da Vinci™ Femtosecond Surgical Laser

Common/Classification name: Ophthalmic Surgical Laser

Establishment Name:
SIE LTD. SURGICAL INSTRUMENT ENGINEERING
Allmendstr. 11
Port/Biel, SWITZERLAND 2562

Registration Number: Pending Registration

Regulatory Class: Class II

Classification Name: Ophthalmic Laser

Regulation Number: 21 CFR 878.4810, 886.4370

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Product Code: GEX, HNO

Reviewing Panel: Ophthalmic Devices

Indications for Use: The Da Vinci™ Femtosecond Surgical Laser is an ophthalmic surgical laser indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

Performance Standards: The Da Vinci™ Femtosecond Surgical Laser is in full compliance with FDA's Performance Standard for Light-emitting Products; 21 CFR §1040.10 and 1040.11.

Device Description: The Da Vinci™ Femtosecond Surgical Laser is a precision ophthalmic surgical laser designed for use in performing lamellar corneal resections. The cutting action of the Da Vinci™ Femtosecond Surgical Laser is achieved through nonlinear absorption of infrared laser light and subsequent disintegration of tissue, created by focused ultrashort pulses which are delivered through a lens while fixating the eye under a vacuum.

The complete Da Vinci™ Femtosecond Surgical Laser system consists of the following functional units:

1. **Base Station** (BS), integrating the Laser Unit, Fast Scan Unit (FS), and Fixed Mirror Articulating Arm (FMAA)
2. **Handpiece** (HP), integrating the Slow Scan Unit (SS) and the Cutting Lens
3. **Accessories**, comprising Suction Ring, Distance Foil, Vacuum Tube with Strainer and Handpiece Cover

The Da Vinci™ Femtosecond Surgical Laser is movable on four rollers. Two rollers can be locked by a mechanical brake. For movement inside the clinic, HP and FMAA can be locked in a secured transport position.

Base Station

The Base Station is in a position perpendicular to the patient's body axis, allowing manipulation of the FMAA from both sides of the BS. The Base Station is height adjustable in a way as to allow positioning of the shoulder (middle) joint at 950–1250mm above ground. This allows the adjustment of the system to different types of patient couches and Excimer lasers within a range of 300mm. The nominal reference height is 1000mm.

On the table of the Base Station there is park position where HP and forearm of the FMAA are locked when the system is not in operation. In this park position the accessories, i.e. the distances foil DF, the suction ring SR and the vacuum tubing can be mounted comfortably.

The Da Vinci™ Femtosecond Surgical Laser has a protective housing that prevents unintentional access to laser radiation.

Fixed mirror articulating arm

The FMAA consists of two arm elements (upper and lower arm) and three joints (shoulder, elbow and hand) connecting the HP to the BS. Thus, the HP can easily be moved by the user in all 6 degrees of freedom of the space.

The FMAA is balanced in a way as to hold the residual net force, i.e., without external force on HP or of FMAA on eye, at < ±2N. Thus the stress upon the eye is minimized.

In the working position all links of the Fixed Mirror Articulating Arm are aligned roughly in a right angle (i.e. at 90° ±30°). During resection the elbow of the Fixed Mirror Articulating Arm is positioned roughly above the torso of the patient. These positions allow optimal manual control of the FMAA with the HP.

To prevent uncontrolled rotation around the shoulder joint, the upper arm of the FMAA can be inserted in a special clamp mounted below the touch screen, from where it can be removed manually by the user requiring a force of <5N. The limitation of the tractive force allows the operator to remove the FMAA from the clamp by holding the HP. During transportation inside the clinic, the clamp protects the FMAA from excessive strain and vibration. The clamp further provides vertical support of about 50N to the FMAA. For transports outside the clinic, the FMAA is to be unmounted.

Electronic Control System

Several features ensure permanent control of the Da Vinci™ Femtosecond Surgical Laser and an immediate shut-down in case of malfunction of a system component:

Master ON Switch. The Base Station is turned on by a Master ON Switch. This switch can remain ON even if the system is not used for a long time.

Softstart: The system is started by pressing the softstart button on stand of the touch screen. As soon as the internal power supplies are powered, a green LED indicator on the stand of the touch screen indicates "power ON".

Shutdown: The system is switched OFF by software control. After the shutdown procedure all major parts are powerless.

Watchdog System. The entire electronic system is permanently checked by an independent hardware system. If any critical software task does not response in less than 1 second, the system automatically shuts down the critical components (laser module, shutter, fast scan, height adjustment).

Laser Enabling. When the softstart button is pressed, after a short start-up sequence the Da Vinci™ Femtosecond Surgical Laser System Window appears on the touch screen and requests a login name and password. Laser emission is disabled until the user selects appropriate treatment parameters and all internal control parameters are checked.

Laser Ready Indicator: As soon as the internal laser module generates laser light, a yellow LED indicator on the stand of the touch screen lights.

Laser Emission Indicator. Laser emission is indicated by a red LED indicator located on the stand of the touch screen.

Safety Shutter. The laser module is always completely shut down, except 1 minute prior to and during resection. A safety shutter controls the laser emission during operation. The shutter is monitored by two sensors indicating correct operation.

Emergency OFF Button. The Emergency OFF Button is a red button located on top of the table of the base station and reachable from all operating positions. When pressed, the button directly, i.e. without any use of software, shuts off all critical components, i.e. mainly the laser module. This control should be used only in the event of an emergency.

Software. The software of the Da Vinci™ Femtosecond Surgical Laser is configured in such a way as to prevent errors and maladjustments to a large extent. Access via graphical user interface is restricted to the program level, i.e., the operators cannot see the operating system level of the controls. Similarly, critical parameters are only accessible to special service users (password protected).

The text on the graphical user interface is available in English. The main steps of the procedure are confirmed by voice confirmation.

Laser: The internal laser module is a Class 4 laser product, the laser output radiation is Class 3B.

Handpiece
The working position of the Handpiece is located in the focus of the operating microscope of the Excimer Laser. A dedicated viewing window on the top of the HP allows the operator an almost undisturbed view of the eye through the operating microscope and the HP. Thus the HP with the laser exit windows the suction ring

mounted below can easily be positioned on the patient's eye. LED illumination in the HP provides sufficient light to view the surgical region.

The glass of the viewing window is specially coated in order to block the laser light and thus to protect the observing operator against the minimum stray light.

During laser resection the handpiece is in a horizontal position and approximately perpendicular to the patient's body axis. Disturbing contours within the environment of the eye are thus largely avoided.

Accessories

Suction Ring

The reusable Suction Ring (SR) connects the HP to the eye during resection. The Suction Ring is held to the eye by the force of a vacuum. The vacuum tubing connects the Suction Ring to the vacuum supply inside the Base Station.

Design, materials, cleaning and sterilization procedures of the Suction Ring are identical to the SR used with the Amadeus Microkeratome cleared under K993190.

Distance Foil

The foil is an adhesive film made of medical grade plastic..

Vacuum Tube with Strainer

The sterile vacuum tube consists of a strainer, the tube, and a connector to the Base Station.

Handpiece Covers

The two Handpiece Covers (front and rear) ensure the sterility of the handgrip on the HP. They are slid over the HP body and mechanically interlocked, are reusable and autoclavable.

Footswitch

The casting footswitch is an UL 2601.1, DIN EN and CAN/CAS conforming off-the-shelf product.

The footswitch cannot be activated unless all steps in preparation for resection are completed.

Test Body

The disposable Test Body is used for the daily functional control of the Da Vinci™ Femtosecond Surgical Laser and is destroyed by the test.

Method of Resection

Prior to resection the eye is flattened by the laser exit window and fixed by vacuum to maintain a precise distance from cutting lens to focal point. The maximum depth of the focal point is at 250 µm ± 5 µm minus the thickness of the distance foil (e.g. 110 µm), thus preventing cuts into the endothel. The fixation of the eye is achieved by a vacuum which is generated applied to a suction ring. The resulting applanated surface and thus the flap diameter are determined by the geometry of the suction ring.

The corneal flap is created by the software controlled xy-scanner (Slow Scan) which moves the cutting lens inside the HP over the flattened surface following a meander-like scanning pattern (Slow Scan trajectory). Simultaneously to this Slow Scan motion, the laser beam oscillates perpendicular to this trajectory (*Fast Scan* trajectory). The Fast Scan frequency is adjustable. The surgical effect is achieved through nonlinear absorption of infrared laser light and subsequent disintegration of molecular bonds.

Substantial Equivalence

The technical characteristics of the Da Vinci™ Femtosecond Surgical Laser are substantially equivalent to those of the Pulsion FS Laser of IntraLase Corp. cleared under K013941. The intended use and the indication for use are identical to those of the Amadeus Microkeratome cleared under K993190.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2006

SIE Ltd. Surgical Instrument Engineering
c/o Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
13 Red Fox Lane
Littleton, CO 80127

Re: K053511
Trade/Device Name: Da Vinci™ Femtosecond Surgical Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, HNO
Dated: February 16, 2006
Received: February 17, 2006

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Acting Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053511

Device Name: Da Vinci™ Femtosecond Surgical Laser

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3-6-2006

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K053511